UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,705	11/07/2000	Kenji Sakamoto	IKU0104PUSA	2404

7590 10/01/2004

James N Kallis
Brooks & Kushman
Twenty Second Floor
1000 Town Center
Southfield, MI 48075

EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/647,705	SAKAMOTO, KENJI	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/21/04.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/2/01
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action filed on July 21, 2004 has been entered.

2. Claims 1, 4, 23-25 are pending. Claims 2-3, 18-22 are cancelled. Claims 5-17 are withdrawn.

3. This application is filed on November 7, 2000.

Response to Arguments

4. Applicant's response to the office action is fully considered and is found not persuasive.

5. The following is the rejection made in the previous office action under 35 USC 102(b):

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ali et al. (J. Biol. Chem., Vol. 266, No. 30, pp 20110-20117, 1991).

Ali et al. teach a method of claim1, of searching for a physiologically active peptides, wherein Ali et al. disclose that the method comprises

(a) comparing the cDNA sequences of receptor variants (prolactin (PRL) receptor variants) of receptors having one or more variant sizes (PRL long and short forms) (see page 20112, column 1, paragraph 1 and 2 of results section, Fig 1, page 20113, Figs. 2 and 4) the receptor being an identical ligand and being products of the same gene (prolactin gene) wherein a cell present in vivo (immune cell, interleukins) acts an antagonist to the ligand for the receptor (see page 20110, column 2, lines 20-26 of paragraph 1);

(b) identifying which cDNA sequence in the larger receptor is missing in the shorter receptor (see page 20112, column 1, lines 14-26, column 2, lines 1-11 of paragraph 1 of results section);

(c) determining the corresponding peptide sequence from cDNA sequence of missing region (see page 20113, Fig 2, and Fig 3, column 1, lines 14, column 2, lines 1-6, identifying the missing region by comparing the nucleotide sequence and corresponding amino acid sequence);

(d) synthesizing a peptide (isolation of peptide) having at least 70% homology (see page 20114, column 1, lines 3-4 of paragraph 1, page 20111, column 2, lines 1-13 of paragraph 4 under subheading nucleic acid hybridization screening and sequencing, page 20112, column 2, lines 1-19 of cloning and characterization of a cDNA for Nb2 PRL receptor, page 20113, lines 11-14, wherein Nb2 PRL-R cDNA indicates 70% homology retention);

(e) testing (characterization of activity) said peptide PRL-R (short form) for activity as an antagonist to the cell which expresses the receptor of the ligand (see transient transfection results on page 20114, column 1, lines 3-15, column 2, lines 1-3, paragraph 1, page 20115, column 2, lines 2-12).

Thus the disclosure of Ali et al. meets the limitations in the instant claims.

Response to arguments:

Applicants' arguments with regard to the above rejection are fully considered and found not persuasive. Applicants argue that Ali et al. does not teach a peptide having 70% homology and assert that Ali et al. does not disclose synthesis of a peptide corresponding to missing region. These arguments are fully considered and found not persuasive because Ali et al. teach a method for synthesizing peptide variants having 70% homology and a peptide having 70% homology. Ali et al. reference disclose the synthesis of the missing region as shown in Fig.1, panel C, wherein the missing region is identified in cytoplasmic domain, and Fig. 4 of Ali et al. disclosure identifies two receptors having 70% homology to the corresponding nucleotide sequence with

the areas including missing segment. Ali et al. also disclose that the missing region corresponds to exon 10 of prolactin receptor gene (see page 20114, col. 2, paragraph 2). Thus the disclosure of Ali et al. anticipates the limitations in claim 1 and therefore the rejection is maintained herein.

6. The following is the rejection made in the previous office action under 35 USC 103(a):

Claims 4,23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ali et al. (J. Biol. Chem., Vol. 266, No. 30, pp 20110-20117, 1991) in view of Kelly et al. (USPN. 6,083,753).

Ali et al. teach a method of claims 4, 23-25, of searching for physiologically active peptides, wherein Ali et al. disclose that the method comprises

(a) comparing the cDNA sequences of receptor variants (prolactin (PRL) receptor variants) of receptors having one or more variant sizes (PRL long and short forms) (see page 20112, column 1, paragraph 1 and 2 of results section, Fig 1, page 20113, Figs. 2 and 4) the receptor being an identical ligand and being products of the same gene (prolactin gene) wherein a cell present in vivo (immune cell, interleukins) acts an antagonist to the ligand for the receptor (see page 20110, column 2, lines 20-26 of paragraph 1);

(b) identifying which cDNA sequence in the larger receptor is missing in the shorter receptor (see page 20112, column 1, lines 14-26, column 2, lines 1-11 of paragraph 1 of results section);

(c) determining the corresponding peptide sequence from cDNA sequence of missing region (see page 20113, Fig 2, and Fig 3, column 1, lines 14, column 2, lines 1-6, identifying the missing region by comparing the nucleotide sequence and corresponding amino acid sequence);

(d) synthesizing a peptide (isolation of peptide) having at least 70% homology (see page 20114, column 1, lines 3-4 of paragraph 1, page 20111, column 2, lines 1-13 of paragraph 4 under subheading nucleic acid hybridization screening and sequencing, page 20112, column 2, lines 1-19 of cloning and characterization of a cDNA for Nb2 PRL receptor, page 20113, lines 11-14, wherein Nb2 PRL-R cDNA indicates 70% homology retention);

(e) testing (characterization of activity) said peptide PRL-R (short form) for activity as an antagonist to the cell which expresses the receptor of the ligand (see transient transfection results on page 20114, column 1, lines 3-15, column 2, lines 1-3, paragraph 1, page 20115, column 2, lines 2-12). However Ali et al. did not teach chemical synthesis of said peptide and peptide fragments having 80%-90% homology.

Kelly et al teach identification of soluble human PRL-R (prolactin receptor) variants, wherein Kelly et al. disclose that said peptide receptor could be obtained from natural sources, or could be chemically synthesized (see column 5, lines 34-40); Kelly et al. also disclose that different peptide variants of PRLR (muteins) comprise one or more amino acid substitutions or deletions with substantial or same biological activity and such variants can be produced by conventional mutagenesis techniques, which comprise peptides having 80%-90% homology to PRLR (see column 5, lines 8-19, 47-67, column 6, lines 1-7, column 8, lines 9-28).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of searching for physiologically active peptides as taught by Ali et al. with the method of producing variant peptides as taught by Kelly et al. to achieve expected advantage of developing an improved method for searching and producing physiologically active peptides because Kelly et al. taught that biologically active

peptide variants can be produced by substitution or deletion of one or more amino acids and the biological activity includes binding activity (enhanced or inhibitory activity) (see column 5, lines 50-61). An ordinary practitioner would have been motivated to combine the method of Ali et al. with the method of Kelly et al. to enhance the searching for wider range of physiologically active peptides by incorporating the variant peptides (80%/90% homology fragments), which would result in a sensitive method of searching physiologically active peptides including mutant forms.

Response to arguments:

Applicants' arguments with regard to the above rejection are fully considered and found not persuasive. Applicants argue that neither Ali et al. nor Kelly et al. disclose the synthesis of a peptide having at least 70% homology to the missing region and thus the claims are not obvious over Ali et al. in view of Kelly et al. Applicants' arguments are fully considered and found not persuasive. As discussed above, Ali et al. does disclose a method for synthesis of a peptide variants having 70% homology to the missing region. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In this case, specific motivation is provided in the rejection above, wherein Kelly et al. taught that biologically active peptide variants can be produced by substitution or deletion of one or more amino acids and the biological activity includes binding activity (enhanced or inhibitory activity) (see column 5, lines 50-61). An

ordinary practitioner would have been motivated to combine the method of Ali et al. with the method of Kelly et al. to enhance the searching for wider range of physiologically active peptides by incorporating the variant peptides (80%/90% homology fragments), which would result in a sensitive method of searching physiologically active peptides including mutant forms. Therefore the rejection is maintained herein.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Benzion reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
September 16, 2004

JEFFREY FREDMAN
PRIMARY EXAMINER
9/19/04